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The Honorable Colm F. Connolly
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

REDACTED - PUBLIC VERSION

Re: *In re: Palbociclib Patent Litigation*, MDL No. 19-2912 (CFC);
Pfizer Inc., et al. v. Aizant Drug Research Sols. Pvt. Ltd., et al.,
C.A. No. 19-743 (CFC) (consolidated)

Dear Judge Connolly:

Defendants Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Cadila Healthcare Limited (collectively, "Zydus") improperly refuse to provide substantive responses to Plaintiffs' Interrogatory Nos. 1-4, which seek Zydus's bases for its non-infringement assertions, and No. 9, which relates to its market research for products embodying the invention, prior to deposition of Zydus's witnesses.[1]

1. Interrogatory Nos. 1-4

This is a Hatch-Waxman case in which thirteen Defendants filed ANDAs to market a generic version of Pfizer's drug Ibrance® (palbociclib), and Plaintiffs have asserted patents that cover the palbociclib compound. Zydus asserts that its generic palbociclib product ("ANDA Product") will not infringe the claims of the Asserted Patents and maintains non-infringement as an affirmative defense, D.I. 110 at 28, [redacted] Plaintiffs—more than 10 months ago—served Interrogatories Nos. 1-4 on all Defendants, asking them to describe, "on

[1] One day before Plaintiffs' letter brief was due, and months after Plaintiffs first raised the issue, [redacted] Such stipulation would moot the dispute with respect to Interrogatory Nos. 1-4 but not with respect to Interrogatory No. 9.

a claim-by-claim basis," the bases for their contention that their ANDA Product would not infringe the asserted claims. Ex. A at 12-14. Zydus refused to provide a substantive response, stating that its ANDA product "will not infringe each of the asserted claims . . . because an invalid claim cannot be infringed," but then hedging that its "investigation continues" and it "will provide its expert reports consistent with the Court's Scheduling Order." *Id.* at 12-14. Plaintiffs also served Requests for Admissions ("RFA") asking Zydus to admit that its ANDA product meets the asserted claims, but here too, Zydus elided, [redacted] and then denying the RFA. Ex. B at 4-5.

For months, Plaintiffs have pushed Zydus to supplement its responses to disclose any non-infringement theory. In a June 29 letter to all Defendants, Plaintiffs explained that "[m]any of the individual Defendant's current responses . . . are equivocal and offer no basis for non-infringement other than the alleged invalidity of the asserted patents," and asked for supplementation. Ex. C. Defendants collectively agreed to supplement their interrogatory answers on non-infringement by August 10. Ex. D. Zydus, however, not only failed to supplement by August 10, but later refused to even provide a date by which it would do so. Ex. E.

Now, with depositions imminent and the close of fact discovery approaching, Zydus should be required to disclose all bases for its non-infringement position, or unequivocally state that it will not contest infringement of the asserted claims. Plaintiffs have "the right to obtain the factual basis for each of [Defendant's] affirmative defenses beyond the bare assertions of them in [Defendant's] responsive pleading." *Wi-Lan Inc. v. Hulu, Inc.*, C.A. No. 15-788-LPS, Oral Order (D.I. 204) (D. Del. Apr. 13, 2018) (Ex. F). And yet, after nearly a year of fact discovery, Plaintiffs have nothing more than Zydus's "bare assertions." Its evasive discovery responses fail to clarify whether it has an as-yet undisclosed theory of non-infringement that it intends to raise, or if it in fact has *no* bases for non-infringement—despite its repeated assertions otherwise.

Zydus's continued refusal to disclose its supposed non-infringement theory (or lack thereof) prejudices Plaintiffs. "Interrogatories are necessary to advance the orderly pretrial development of the case and prohibiting Plaintiff from benefiting from this discovery mechanism would be unfairly prejudicial to Plaintiff and disrupt the Court's management of the case." *Wi-Lan Inc.*, D.I. 204 (Ex. F); *see also Magnolia Med. Techs. Inc. v. Kurin, Inc.*, C.A. No. 19-97-CFC-CJB, D.I. 96 (D. Del. Jul. 1, 2020) (ordering defendants to provide a "written limitation-by-limitation response" on invalidity) (Ex. G). Because Zydus has not disclosed its non-infringement theory, Plaintiffs cannot test that theory with Zydus's corporate and fact witnesses. That

would allow Zydus to spring a previously undisclosed non-infringement theory at the close of fact discovery or through its expert reports, effectively denying Plaintiffs any opportunity to question witnesses knowledgeable about Zydus's ANDA Product and examine the factual bases of its theory. On the other hand, if Zydus has no non-infringement theory and would so state, it would avoid some depositions, corporate topics and expert discovery.

Throughout the meet and confer process, Zydus has offered no justification for its refusal, suggesting only that it will eventually disclose its theory. But "Rule 33 does not permit a party to unilaterally set its own deadline to respond to an interrogatory." *Magnolia Med. Techs. Inc.*, D.I. 96 (Ex. G). The Court should therefore order Zydus to supplement its responses to Interrogatory Nos. 1-4.[2]

2. Interrogatory No. 9.

Zydus has similarly refused to answer Interrogatory No. 9, which asks it to identify and describe market research it "undertook, purchased, or commissioned related to any product containing palbociclib, including Ibrance®." Ex H at 9-10. Zydus did not answer, instead objecting on relevance and proportionality grounds. *Id*. These objections are meritless. There is no serious dispute that Zydus's market research for products containing palbociclib, including information on commercial sales and market share, is relevant to the objective indicia of non-obviousness—specifically, the commercial success of palbociclib. *See, e.g.*, *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1371 (Fed. Cir. 2012) (affirming district court finding of non-obviousness based on market share data); *Leo Pharm. Prod., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013) (reversing obviousness decision based on commercial success of the embodying product).

Moreover, the Defendants—including Zydus—jointly served a nearly *identical* interrogatory seeking "all market research that Plaintiffs undertook, purchased, or commissioned related to Ibrance®." Ex J at 7. That alone should foreclose Zydus's argument that market research for palbociclib is somehow irrelevant or disproportional to the needs of the case.

The Court should therefore order Zydus to supplement Interrogatory No. 9.

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[2] This Court addressed this very issue with Zydus in another case, where Zydus also refused "to provide the bases for its noninfringement positions." *Pharmacyclics LLC v. Fresenius Kabi USA, LLC*, C.A. No. 18-192-CFC-CJB, D.I. 192 at 3 (Ex. I).

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac
Attachments

cc: Counsel of Record (via electronic mail; w/attachments)

CERTIFICATION

The undersigned counsel hereby certifies that the foregoing letter is in 14-point Times New Roman font in accordance with the November 6, 2019 Standing Order Regarding Briefing in All Cases and that it is three pages, pursuant to the Court's page limits in Paragraph 12(a) of the Scheduling Order.

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)